REMARKS

Entry of the foregoing amendments are respectfully requested in light of the remarks which follow.

As noted in the Office Action Summary, claims 16-31 and 34 are currently pending. Claims 16, 21, 27, and 29 are amended herein. Claims 19 and 31 are cancelled as redundant in light of amendments made herein. New claims 35-60 have been added. Basis for these amendments may be found throughout the specification and claims as-filed, especially at page 5, lines 15-19 (regarding the fatty component) and page 5, line 25 to page 6, line 6 (regarding hydrophilic components) and claim 1 as previously searched and examined by the Examiner. Thus, the new claims do not raise new issues requiring a further search. Thus, no prohibited new matter is presented herein. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled by way of the present Amendment.

Rejections Under 35 U.S.C. § 112

Applicants appreciate that the Examiner has withdrawn the indefiniteness rejection as it pertains to claim 25. However, claims 16 and 27 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite.

In the interest of expediting prosecution, and without acquiescing in the rejection, independent claims 16 and 27 are amended herein to recite that the hydrophilic component is xanthan gum, guar gum, acacia, or any combination thereof. These hydrophilic components are supported by the specification, at least on page 6, lines 3 to 4.

In light of the above remarks and amendments to the claims, Applicants request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 16, 24, and 29-30 stand rejected under 35 U.S.C. § 102 as purportedly anticipated by Yajima *et al.* (U.S. Patent No. 5,707,646; "Yajima"). Applicants respectfully traverse this rejection.

Applicants submit that Yajima fails to recite every element of the presently claimed invention. To anticipate a claim, a single prior art reference must teach each and every element of the claimed invention. *See* M.P.E.P. § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *Hybritech Inc.v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

Independent claims 16 and 27 are amended herein to provide further clarification that the fatty component of the claimed formulation is behenic acid, glycerol behenate or a combination thereof. Yajima does not teach behenic acid, glycerol behenate or a combination thereof. Thus, the present claims are structurally distinguishable from what is disclosed in Yajima.

Claims 16, 19, 24-25, and 27-33 stand rejected under 35 U.S.C. § 102 as purportedly anticipated by Briskin *et al.* (WO 95/223109; "Briskin"). Applicants respectfully traverse this rejection.

Briskin fails to recite each element of the present invention as claimed herein. Independent claims 16 and 27 recite xanthan gum, guar gum, acacia, or any

combination thereof, as the hydrophilic component of the invention. Briskin does not teach or suggest these elements.

In light of the above amendments to the claims, Applicants submit that Briskin fails to recite each element of the present claims, and request that the rejections under 35 U.S.C. § 102 be withdrawn.

Rejections Under 35 U.S.C. § 103

Applicants appreciate that the Examiner has withdrawn the obviousness rejections pertaining to claims 16-18 and 24-30 as being unpatentable over US patent 6,117,452 to Ahlgren *et al.*, and rejection of claim 22 as being unpatentable over US patent 6,117,452 to Ahlgren *et al.* in view of Gibson *et al.* (5,811,120). Although the rejection of claim 21 as being unpatentable over Yajima is withdrawn, the rejection of claims 17-18, 20-21, 23, and 25-28 are maintained. Applicant respectfully traverses this rejection.

For a *prima facie* case of obviousness, the following three requirements must be met. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine the reference with another reference. Second, the proposed modification must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Third, the prior art reference must teach or suggest all the limitations of the claims. The teachings or suggestions as well as the expectation of success must come from the prior art and not from applicant's disclosure. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596,

1598 (Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); and *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Applicant respectfully submits that these criteria have not been met in the present Office Action.

As discussed above, Yajima fails to disclose each element as claimed in the present invention. For example, Yajima does not teach or suggest xanthan gum, guar gum, acacia, or a combination thereof. Without a teaching of these elements, there is no motivation to combine Yajima and utilize xanthan gum, guar gum, acacia, or a combination thereof in place of the hydrophilic components taught in Yajima. Applicants respectfully request that this rejection be withdrawn.

The Examiner further rejects claims 17-18, 20-23, 26 and 34 under 35 U.S.C. § 103 as being unpatentable over WO 95/22319 to Briskin *et al.* in view of Gibson *et al.* (US 5,811,120; "Gibson"). Applicants respectfully traverse this rejection.

Briskin and Gibson fail to teach or suggest each element as recited in the claims. For example, neither Briskin nor Gibson teach or suggest the elements of xanthan gum, guar gum, acacia, or any combination thereof as recited in Applicant's Claim 16 (upon which claims 17-18, 20-21 and 23 depend). Without a teaching of these elements, there is no motivation to combine Briskin and Gibson and utilize xanthan gum, guar gum, acacia, or a combination thereof in place of the hydrophilic components taught in Briskin and Gibson, namely hydroxypropyl cellulose and raloxifene, respectively.

The Examiner suggests that a combination of the references would result in the claimed invention. However, there is no suggestion in any of the references for the proposed combination. As the CAFC stated in *ACS Hospital Systems Inc. v. Montefiore Hospital*, 221 USPQ 929, 933 (1984):

> Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section §103, teachings of references can be combined *only* if there is some suggestion or incentive to do so.

Furthermore, in *In re Gordon*, 221 USPQ 1125, 1127 (Fed.Cir. 1984), *citing In re Semaker,* 217 USPQ 1, 6-7 (Fed. Cir. 1983) and *In re Imperato*, 179 USPQ 730, 732 (CCPA 1973):

> The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.

In light of the above comments, Applicants request that this rejection be withdrawn.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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